



UNITED STATES PATENT AND TRADEMARK OFFICE

mv
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,989	09/18/2000	Robert Charles Susil	55106 (71699)	4542
21874	7590	04/22/2004		
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER JUNG, WILLIAM C	
			ART UNIT 3737	PAPER NUMBER 15
DATE MAILED: 04/22/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/663,989

Applicant(s)

SUSIL ET AL.

Examiner

William Jung

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 13-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Response to Arguments

Applicant's arguments with respect to claims 1-44 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

1. Claims 11 and 12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 3. See MPEP § 608.01(n). Accordingly, the claims 11 and 12 have not been further treated on the merits.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 8, 9, 35, 36, 43 and 44 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a non-coplanar arrangement of three fiducial markers asserted utility or a well established utility.

Claimed element where three fiducial objects are in a non-coplanar arrangement is not possible. Any three points in space are must lie in a same plane.

Claims 8, 9, 35, 36, 43 and 44 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a non-coplanar arrangement of three fiducial markers asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-10, 13-23, 28, 30-35, and 37-44 are rejected under 35 U.S.C. 102(b) as being anticipated by *Kalfas et al* (US 5,776,064).

Claims 1, 8, 9, 13, 16, 17, 32, 33, 35, and 39-44: Kalfas et al anticipate all claimed elements in claims 1, 8, 9, 13, 16, 17, 32, 33, 35, and 39-44. Kalfas et al disclose method and apparatus where an imaging system (Computed Tomography) is utilized with the medical instrument or tool such as needle 42 as shown in figures 1B and 2 (image guided) to invasively place the needle in a patient marked with stereotactical frame where the location of the needle can be tracked to references frame (coordinates) in view of the imaging coordinates as shown in figures 1B and 6A (col. 2, line 59 –col. 3, line 39; col. 7, line 41 – col. 8, line 34). Fiducial markers 164 in figure 1B provide reference frame where the translated frames of 3D data or image in figures 1B and 6A effectively becomes cross sectional slice showing the surgical instrument and the target 168 where the needle is guided to by calibration and feedback from combination of 110, 130, and 160.

Claims 2-7, 14, 15, 18, 19, 20, 30, 31, 34, and 38: Kalfas et al's apparatus and method above further disclose that the surgical or therapeutically instrument is in the field of view of the imaging system and the motion of the instrument is register with the three fiducial marker and

controls the movement of the instrument by feedback via images of surgical instrument on display.

Claims 10 and 37: Kalfas et al disclose where the surgical instrument is a wand manipulated in hand by a surgeon (col. 8, lines 35-45).

Claims 21-23: CT or MRI images are inherently taken in slices or frames multiple image acquisition to form 3D image data. Therefore, the speed of the frame determines the time period of the image and more slices is required the more time would be required.

Claim 28: Biopsy procedure as anticipated by Kalfas et al includes removal of tissue, a definition of biopsy or tissue sampling.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 24-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Gillies et al* (US 6,272,370) as applied to claim 16 above, and further in view of *Kalfas et al* (US 5,776,064).

Kalfas et al substantially disclose all claimed features in claims 24 and 25. However, Kalfas et al do not disclose specific method where the invasive surgical instrument is used to deposit a material such as therapeutic agent. In Gillies et al's invention, a stereotactical device such as needle biopsy is used with CT or imaging system as guidance to a target location where the drug delivery or depositing of therapeutical material is performed. In addition, Gillies et al

also disclose application of heat or energy as therapy method. Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Gillies et al's therapeutic injection via invasive tools such as needle biopsy to Kalfas et al method described above to achieve the claimed invention in claims 24-27 and 29.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Truwit (US 6,206,890), *Gueziec et al* (US 5,951,475), and *Omurtag et al* (US 6,132,437)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung whose telephone number is 703-605-4364. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

WJ
April 12, 2004

Angela D. Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700